


DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

Centers for Disease Control and Prevention
Office of Health and Safety, MS A-46
Atlanta, Georgia 30333
TEL: 404-718-2077; FAX: 404-718-2093



Permit to Import or Transfer Etiological Agents or Vectors of Human Disease

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in Item 1 below.

PHS PERMIT NO.	2006-12-002	
DATES	ISSUED: Friday, December 01, 2006	EXPIRES: Saturday, December 01, 2007
1. DESCRIPTION OF MATERIAL	ISOLATES OF ETIOLOGIC AGENTS (LIST ON FILE AT CDC); NOT APPROVED FOR SELECT AGENTS AS DEFINED IN 42 CFR 73.	
2. PERMITTEE (NAME, ORGANIZATION, ADDRESS)	ROGER W. PARKER DOD VET. FOOD ANALYSIS & DIAGNOSTIC LAB. 2472 SCHOFIELD RD., BLDG. 2630 FORT SAM HOUSTON, TX 78234-6232 TEL: 210-295-4604 FAX: 210-270-2559	
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	BIOTECHNOLOGY FRONTIERS (BTF PTY LTD) 35-41 WATERLOO RD., UNIT 1 NORTHRYDE, AUSTRALIA	
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	<input checked="" type="checkbox"/> Multiple Importation into the US <input type="checkbox"/> Single Transfer Within the US A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.	
5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED	A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. <input checked="" type="checkbox"/> B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals. <input checked="" type="checkbox"/> C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines. <input checked="" type="checkbox"/> D. Additional Requirements: File APHIS/CDC Form 2 for select agents as defined in 42 CFR 73 IATA Packaged to preclude escape. <input checked="" type="checkbox"/> USDA permit may be required (Telephone: 301-734-3277). <input checked="" type="checkbox"/> E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories." <input checked="" type="checkbox"/> F. Packaging must conform to 42 CFR Section 72 and 49 CFR Sections 171-180. G. Select Agent. Receiving facility must be registered under 42 CFR Part 73.	
6. COPY SENT TO <input checked="" type="checkbox"/> U.S. QUARANTINE STATION	7. Signature of issuing officer  Paul P. Mehta, M.D., Health Scientist, Etiologic Agent Import Permit Program	

CDC 0728 (F 13.40) REV. 2-91

42 CFR 71.54. Etiological agents, hosts, and vectors

- (a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.
- (b) Any import coming within the provisions of the section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Note: Other permits may be required.



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Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

To: Permittee, Public Health Service Import Permit

Re: Permit issued under 42 CFR Part 71.54 ("Etiological agents, hosts, and vectors")

Please find enclosed the U.S. Public Health Service import permit you have requested. Be reminded that the permittee must ensure that:

1. The enclosed import permit and labels are forwarded to the shipper(s). The enclosed permit and labels may be photocopied if more are needed.
2. One enclosed label (or copy of label) must be affixed to the outer shipping container.
3. The import permit must accompany the shipping documents.
4. A record of each importation (including permits and shipping documents) is maintained on permanent file.
5. The appropriate shipping and packaging regulations/guidelines are followed and that any other required import permit(s) are obtained (see below for guidance).
6. If select agent(s) or toxin(s) as defined in 42 CFR 73 are identified as contained in a specimen presented for diagnosis or verification, an APHIS/CDC Form 2 must be submitted for prior transfer approval with CDC's Select Agent Program in accordance with Title 42 Code of Federal Regulations, Part 73. Additional information on the CDC Select Agent Program may be found at: <http://www.cdc.gov/od/sap>.

The issuance of an import permit is not an authorization to hand carry the material. If you determine that your imported material meets the definition of Dangerous Goods, and your shipment is subject to the IATA Dangerous Goods Regulations, please be aware that these materials must not be hand carried by passengers or in checked or carry-on baggage. The International Air Transport Association (IATA) Dangerous Goods Regulations (DGR), 46th Edition (2005), Section 2.3.0.1, states that:

"Dangerous goods must not be carried by passengers or crew:

- As or in checked baggage;
- As or in carry-on baggage; or
- On their person,
except as noted in 2.3.2 through 2.3.5."

As defined in IATA Dangerous Goods Regulations, 46th Edition, Section 1.0:

"Dangerous goods are articles or substances which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in these Regulations or which are classified according to these Regulations. "

Section 3.6.0 classifies toxic and infectious substances as dangerous goods Class 6, Division 6.1 and 6.2. As defined in 3.6.2.1: Division 6.2 includes substances which are infectious to humans and/or animals, genetically modified micro-organisms and organisms, biological products, diagnostic specimens and clinical and medical waste, as described in 3.6.2.1.1 to 3.6.2.1.4

Helpful information regarding shipping and packaging regulations/guidelines:

1. Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (World Health Organization): <http://www.who.int/emc/biosafety.html>

2. The IATA Dangerous Goods Regulations (International Air Transport Association):
<http://www.iata.org/cargo/dg>
3. Title 49 Code of Federal Regulations, Parts 100 - 185. Hazardous materials regulations (Department of Transportation): <http://hazmat.dot.gov/>
4. Title 42 Code of Federal Regulations, Part 72. Interstate shipment of etiologic agents (Department of Health and Human Services):
<http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>
5. Biosafety in Microbiological and Biomedical Laboratories, 4th Ed. (CDC/NIH):
<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>

Other permits that may be required:

1. United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services, National Center for Import and Export:
<http://www.aphis.usda.gov/vs/ncie/>
2. United States Department of Interior, U.S. Fish and Wildlife Service:
<http://permits.fws.gov>
3. Title 42 Code of Federal Regulations, Part 73. Possession, Use, and Transfer of Select Agents and Toxins; Final Rule, (Department of Health and Human Services):
<http://www.cdc.gov/od/sap>
4. Title 9 Code of Federal Regulations, Part 121. Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule, (U.S. Department of Agriculture):
http://www.aphis.usda.gov/programs/ag_selectagent/index.html

Etiologic Agent Import Permit Program
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Tel: (404)718-2077 / FAX: (404)718-2093/ Website: <http://www.cdc.gov/od/eaipp/>

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